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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/930,235	02/23/1998	ANJA EITRICH	BEIERSDORF45	2748
27384	7590	12/14/2005	EXAMINER	
NORRIS, MCLAUGHLIN & MARCUS, PA 875 THIRD AVENUE 18TH FLOOR NEW YORK, NY 10022			METZMAIER, DANIEL S	
			ART UNIT	PAPER NUMBER
			1712	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

08/930,235

**Applicant(s)**

EITRICH ET AL.

**Examiner**

Daniel S. Metzmaier

**Art Unit**

1712

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 4-11 are pending.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 November 2005 has been entered.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 4-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is unclear where in the original specification applicants set forth the concept of each of the emulsifiers specifically listed in claim 4 as a "oil-in-water emulsifier". Furthermore, it is unclear where in the original specification applicants provide for the concept of microemulsions having an oil phase of " $\leq 11.8$  % by weight of the microemulsion", particularly when employing the emulsifiers now claims

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as oil-in-water emulsifiers. Applicants disclose emulsifiers at page 11, lines 7 et seq, and exemplify some of those listed. Applicants have not originally set forth the range of " $\leq 11.8$  % by weight of the microemulsion" for the microemulsions as claimed.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 sets forth a polyethoxylated oil-in-water emulsifiers, and/or polypropoxylated oil-in-water emulsifiers, and/or polyethoxylated and polypropoxylated oil-in-water emulsifiers. Applicants' amendment includes species in the alternative grouping, which are outside of the scope of the genus set forth. Specifically, glyceryl isostearate is not ethoxylated and/or propoxylated. Sorbitan isostearate has an HLB of about 4 to 5 and would be considered a "water-in-oil emulsifier" rather than an "oil-in-water emulsifier"

It is unclear what are the metes and bounds of the subject matter sought for patent since applicants' limitations are inconsistent and indefinite.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 4-11 are rejected under 35 U.S.C. 103(a) as obvious over Affinity Biotech, Inc., WO 91/18669. Affinity Biotech, Inc (examples) discloses microemulsions having the property of being transparent or translucent and having an oil phase concentration of less than or equal to 11.8% by weight. Affinity Biotech, Inc (page 3, lines 25-26) further points out that it is generally known that "More fatty oil generally requires more emulsifier". Said teaching suggests lower concentration oil phase microemulsions are more easily made than high oil phase microemulsions.

Affinity Biotech differs from the claims in the emulsifier(s) employed.

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Applicants (page 15, lines 19-21 of the instant specification) disclose ethoxylated triglycerides with HLB of 11-16. Applicants make no distinction between ethoxylated glycerides as used in the Affinity Biotech reference and the polyethoxylated oil-in-water emulsifiers, and/or polypropoxylated oil-in-water emulsifiers, and/or polyethoxylated and polypropoxylated oil-in-water emulsifiers claimed. Affinity Biotech (page 4, lines 6-28; particularly line 14) teaches the emulsifier HLB is usually 10-15, preferably 11-13. Affinity Biotech further (lines 6-28) teaches polyethylene glycol sorbitan esters such as those claimed.

It would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to employ related emulsifiers specifically taught in the Affinity Biotech reference and taught in Affinity Biotech as having the HLB instantly disclosed for the instantly claimed emulsifiers.

Affinity Biotech, Inc (page 4, lines 29-33; and examples, particularly example 7) further teaches the addition of water-in-oil emulsifiers. Affinity Biotech, Inc makes no distinction between the order of addition of the emulsifiers and the coemulsifiers, said reference contemplates the addition of the water-in-oil emulsifiers followed by the oil-in-water emulsifiers, the oil-in-water emulsifiers followed by the water-in-oil emulsifiers, or the simultaneous addition of emulsifiers into the emulsion.

Furthermore, claim 8 does not define any specific temperature. A microemulsion is defined as a liquid in a liquid. Affinity Biotech, Inc discloses materials, which would at least either melt or dissolve in the oil phase since said reference forms microemulsions.

Applicants have not shown that the particular methods impart a distinction to the compositions. See MPEP § 2113.

Affinity Biotech, Inc (page 4, lines 29-33; and examples, particularly example 7) further teaches the addition of water-in-oil emulsifiers. Affinity Biotech, Inc makes no distinction between the order of addition of the emulsifiers and the coemulsifiers, said reference contemplates the addition of the water-in-oil emulsifiers followed by the oil-in-water emulsifiers, the oil-in-water emulsifiers followed by the water-in-oil emulsifiers, or the simultaneous addition of emulsifiers into the emulsion.

Furthermore, claim 8 does not define any specific temperature. A microemulsion is defined as a liquid in a liquid. Affinity Biotech, Inc discloses materials, which would at least either melt or dissolve in the oil phase since said reference forms microemulsions.

To the extent the sequential use of use of water-in-oil emulsifiers followed by the oil-in-water emulsifiers to the emulsion or the separate heating followed by combining has not been disclosed in the Affinity Biotech, Inc reference, the sequence of adding materials or the of the selection of any order of performing process steps has been held to be *prima facie* obvious in the absence of new or unexpected result. See MPEP 2144.04(IV)(c).

Furthermore, Affinity Biotech (examples) teaches heating to above the PIT and thus causing phase separation. Said phase separation constitutes heating the phases separately followed by mixing. Also, applicants have not shown said step of adding and/or heating to be critical to their invention.

***Response to Arguments***

10. Applicant's arguments filed November 17, 2005 have been fully considered but they are not persuasive.

11. Applicants' amendment includes ethoxylated glycerides, e.g., polyethylene glycol (60) evening primrose glycerides and polyethylene glycol (6) caprylic/caproic glycerides.

12. Applicants (page 9 of the above noted arguments) asserts the Affinity Biotech lacks a teaching of the emulsifiers as now claimed. Said argument is misplaced and has been addressed in the above rejection.

13. Applicants (pages 9 and 10) assert the Affinity Biotech lacks any steps of making the microemulsions. Example 4 of Affinity Biotech teaches heating to phase separation followed by cooling with mixing. Applicants have not shown said different to be unobvious since at the point of phase separation, the aqueous phase is heated separately. Furthermore, the separate heating of the phases is within the skill level of one having ordinary skill in the art at the time of the invention for the advantages of ease of handling and apparatus restrictions.

14. Applicants (page 10) assert the instant examples are surprising in view of the teachings of Affinity Biotech since they form microemulsions when the phases are heated separately. This has not been deemed persuasive since no comparative data to rebut the *prima facie* case of obviousness are presented in the instant examples. Said examples merely show that following the teachings of Affinity Biotech have the level of one having ordinary skill in the art, transparent and/or translucent microemulsions and obvious variations thereof may be formed as in the prior art.



***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel S. Metzmaier whose telephone number is (571) 272-1089. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy P. Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**Daniel S. Metzmaier**  
**Primary Examiner**  
**Art Unit 1712**

DSM